DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 10, 2015

Wright Medical Technology, Incorporated
Ms. Jeanine Redden
Regulatory Affairs Director
1023 Cherry Road
Memphis, Tennessee 38117

Re: K150073
Trade/Device Name: MICRONAIL® Distal Radius System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: January 8, 2015
Received: January 14, 2015

Dear Ms. Redden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K150073

Device Name
MICRONAIL® Distal Radius System

Indications for Use *(Describe)*
The MICRONAIL® Intramedullary Distal Radius System is intended to be used for the fixation of unstable distal radius fractures in which closed reduction is not suitable:
• Joint destruction and/or subluxation visible on x-ray;
• Failed fracture fixation with or without bone graft;
• Osteotomy and repair of distal radius malunion with or without bone graft;
• Displaced or non-displaced fracture which may or may not involve angulation or fragmentation of bone;
• Comminuted articular fractures, shearing fractures of the articular surface, severely comminuted extra-articular fractures, and fractures in which reduction has been lost following fixation with percutaneous pins with or without an external fixator.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the MICRONAIL™ Distal Radius System.

1. Submitted By: Wright Medical Technology, Inc.
1023 Cherry Rd.
Memphis, TN 38117

Date: February 9, 2015

Contact Person: Jeanine Redden
Director, Regulatory Affairs
Phone: 901.867.4522
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jeanine.redden@wmt.com

2. Proprietary Name: MICRONAIL™ Distal Radius System

Common Name: Intramedullary fixation rod

Classification Name and Reference: 21 CFR 888.3020- Class II

Device Product Code, Device Panel: HSB - Orthopedic

3. Predicate Device: K040938 Radial Nail System

4. Device Description

The MICRONAIL™ Distal Radius System was cleared (K040938) as a system consisting of a radial nail, cortical bone screws, buttress pins, and buttress screws. All components are manufactured from titanium alloy, Ti 6Al-4V-ELI. Changes to the subject devices include changes made to the radial nail, buttress screws, and cortical bone screws and availability of sterile and non-sterile devices.

5. Intended Use

The MICRONAIL® Intramedullary Distal Radius System is intended to be used for the fixation of unstable distal radius fractures in which closed reduction is not suitable:

- Joint destruction and/or subluxation visible on x-ray;
- Failed fracture fixation with or without bone graft;
- Osteotomy and repair of distal radius malunion with or without bone graft;
- Displaced or non-displaced fracture which may or may not involve angulation or fragmentation of bone;
- Comminuted articular fractures, shearing fractures of the articular surface, severely comminuted extra-articular fractures, and fractures in which reduction has been lost following fixation with percutaneous pins with or without an external fixator.

6. Technological Characteristics Comparison

The MICRONAIL™ Distal Radius System and the legally marketed predicate Radial Nail System have identical indications, utilize the same instrumentation, and are identical in material. Sterilization methods have been updated to reflect the addition of products that are provided sterile.

7. Substantial Equivalence- Non-Clinical Evidence

Mechanical testing, including Static Bending Strength, as well as FEA analysis has shown that the performance of the subject screw is statistically equivalent or greater than the predicate screw.

8. Substantial Equivalence- Clinical Evidence

N/A

9. Substantial Equivalence- Conclusions

The design characteristics of the subject devices do not raise any new types of questions of safety or effectiveness. From the evidence submitted in this 510(k), the subject devices can be expected to perform at least as well as the predicate systems and are substantially equivalent.